

**Written Testimony Submitted to the
Health Subcommittee of the House Energy & Commerce Committee
Use of Imaging Services: Providing Appropriate Care for Medicare Beneficiaries
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Thank you, Mr. Chairman and distinguished members of the panel for giving me this opportunity to discuss the critical role of imaging in cancer care. My name is Dr. Landis Griffeth. I am the Director of Nuclear Medicine at Baylor University Medical Center in Dallas. I also serve as the Medical Director for the North Texas Clinical PET Institute and, for the past 6 years, the National Medical Director for PET for US Oncology.

My discussion today focuses on the use of advanced medical imaging, Positron Emission Tomography (PET) in particular, in the management of cancer patients. However, I want to make it clear that most of what I am saying extends to the treatment of the other major diseases that take millions of American lives each year, such as cardiac or neurological diseases.

Turning to the role of imaging in cancer, it is important to consider several facts:

1. 42 % of Americans will develop a significant cancer.
2. 52% of those (almost 600,000 a year) will die from their cancer.
3. Death rates from the four most common cancers—lung, breast, prostate and colorectal—continue to decline. Over the past decade, Americans have experienced a 7% decline in mortality from cancer and hundreds of thousands of lives have been saved—and imaging has played an important role in this progress.
4. Imaging is used to diagnose, treat, manage, and predict disease.
5. Many cancer patients will have their cancers detected or diagnosed by medical imaging. More importantly, virtually 100% of cancer patients will have their treatment options determined by the results of one or more advanced imaging tests, and a large percentage of those patients will need multiple types of imaging tests and/or sequential imaging tests over time, to determine how well treatment has worked or whether tumor has recurred. Let me restate this – if you or a family member is diagnosed with a life-threatening cancer tomorrow, it is a virtual certainty that the extent of your disease, the treatment of your disease, and the assessment of whether or not that treatment worked will depend heavily on one or more advanced imaging tests.

The role of imaging in cancer care, in simple terms, is to diagnose and localize tumors, so that optimal decisions can be made about whether and how to pursue surgery, radiation therapy, chemotherapy, or any of the other extremely sophisticated therapeutic modalities that are now being developed at an encouraging pace.

The good news is that, over the past 40 years, along with dramatic advances in cancer treatment strategies, there has been an explosion of technological advances in imaging that have dramatically improved cancer patient care. These advances have led to earlier

detection of cancer, when it is most easily and successfully treated, better selection of the appropriate therapies for each individual patient, better targeting of specific types of therapy, such as radiation therapy and minimally invasive surgeries, and better follow-up of cancer patients after therapy. Advanced imaging techniques such as mammography, sonography, CT, MRI, Nuclear Medicine and PET have played a huge role in helping us achieve better patient care, higher cure rates for limited cancers, and longer – and more productive – survival for patients with more extensive cancers.

While many of these new imaging techniques are expensive, we must consider the costs of imaging relative to the costs of treating cancer without the information that imaging provides and also with an eye to the efficacy of treatment without that vital information.

An imaging test, such as a PET or PET/CT scan may cost \$2000 or so with the current payment schedule – clearly a lot of money. Surgery, radiotherapy, and chemotherapy for a cancer patient can very quickly exceed \$100,000 – clearly significantly more money – and that is without some of the newer and more expensive treatment modalities, such as bone marrow transplantation. One paper published last year in the journal *Cancer Biotherapy and Radiopharmaceuticals*, studying patients evaluated for colon cancer that had spread to the liver, showed that incorporating PET into the work-up of these patients saved \$5,269 per patient. In the US, there are 7000 colon cancer patients in this particular clinical situation. If all 7000 of these patients underwent PET imaging, this would save \$37M. In patients undergoing initial staging evaluation of non-small-cell lung cancer, the global savings would be \$267M (in 2003 dollars). Now I realize that \$37M, or even \$267M, is a very small amount compared to the types of budgets that you folks look at every day, but this is for two small subsets of the patients in this country with cancer and, once again, shows that limiting access to advanced imaging is penny-wise and pound-foolish.

How do PET and other advanced imaging techniques save money? - Typically by showing that another costly procedure, like surgery or radiotherapy, is not indicated, or can be better targeted to improve patient results. The most extreme case would be a patient who is thought to have operable cancer, based on other tests, but in whom PET shows that the tumor has spread to other organs. The fact is that advanced imaging like PET helps make sure patients are treated appropriately.

This isn't just important from a cost-savings perspective; it is simply better patient care. The last thing any patient needs is surgery, radiotherapy, or chemotherapy that is either unnecessary or ineffective. For example, PET imaging can prevent up to half of the needless surgeries performed for lung cancer that is thought to be resectable, but, in fact, is not resectable. Imagine if you had inoperable metastatic cancer and only had six months to live. Would you rather have a \$2000, non-invasive PET/CT scan that told you that it was inoperable, so that you could make the most of the time you had left, or would you rather spend a good part of your last six months recovering from a major surgery that cost \$20,000 and that, in the end, didn't do you any good at all?

In addition, as cancer treatments become more expensive or more toxic to the patient, we need to be able to determine DURING therapy, preferably EARLY during therapy, whether that treatment is working or whether we should switch to a different type of therapy. To pursue a cancer treatment that is not working not only wastes thousands and thousands of dollars, but exposes the patient to needless side effects of treatment and, most importantly, delays the switch to another, hopefully more effective, type of therapy. In most tumors, imaging techniques like PET are the best means we have to determine whether a given treatment is working or not.

Moreover, as our treatments become more sophisticated, whether we are talking about better and better targeting of radiotherapy beams to avoid damage to non-tumor tissue or highly advanced types of gene therapies that very precisely target specific types of tumor cells, we simply cannot aim those big guns of cancer therapy correctly without the appropriate imaging techniques, whether they be CT, MRI, Nuclear Medicine, PET, or some combination of the above.

We also cannot forget that many cancer patients actually DIE from their treatments and from complications relating to their treatments, rather than from their disease. That is an unfortunate sequela of the need to use potentially very toxic agents to kill tumor cells. It is imperative that we use the best tools we have to allow us to target and refine those treatments.

I have been asked specifically to address the rise in utilization, and possible over-utilization, of PET and PET/CT, and to suggest ways to manage that utilization. My own impression is that the rise in utilization is a positive occurrence for patients, as long as it is appropriate utilization. I want to stress that increases in imaging utilization arise primarily from advances in patient care and not inappropriate use and are, in large part due to oncologists becoming more familiar with the use of PET in patient management. The large majority of medical oncologists and radiation oncologists currently practicing were not exposed to this relatively new modality during their training, and it sometimes takes a while for even very smart old dogs to learn new tricks. However, over time, when offered a tool that can be demonstrated to be more effective, and more cost-effective, at helping them make these life and death patient decisions, these physicians will, of course, adopt and utilize that tool.

Another factor in PET's growth has been the increased availability of this equipment – which not long ago was confined to major medical centers – in medium and small communities. I believe that this trend is bound to occur with any new and improved treatment or diagnostic tool, it's just that the growth curve is slower for complicated, sophisticated modalities than it is for something that is easy to explain and distribute, such as a new antibiotic.

It should not be a surprise that the utilization of PET imaging has continued to grow rapidly over the past several years. It takes time to disseminate the knowledge and equipment necessary for appropriate utilization. In fact, even when we use the very stringent criteria developed by CMS for determining eligibility for a PET study, as well

as VERY conservative estimates for the number of patients who will need a follow-up study to assess for effectiveness of treatment or for suspicion of a recurrence, far less than half of those patients who would probably benefit from a PET study are currently getting that PET study. Based on the cost-effectiveness projected for these PET studies, CMS is losing hundreds if not thousands, of dollars on each patient who does not get an appropriate PET scan, because that patient is, therefore, potentially at risk of undergoing other needless, expensive procedures. It is important to understand that imaging technologies detect cancer early, enable less-invasive cancer diagnosis and treatment, foster more effective cancer management, produce efficiencies and savings in cancer care, and, in many instances, keep workers more productive.

There also has been concern expressed over the “escalation of technology and expense,” such as from CT to PET to PET/CT. This process is not just an evolution of technology, but an evolution of patient care. Sometimes, the benefits of this evolution, while clinically evident, are hard to quantify. For example, most studies, depending on the tumor type, show that combined-modality PET/CT scanning will provide answers that may range from 5-30% more accurate than separate PET and CT scans. But, the CONFIDENCE in the answer provided by this new technology can be up to 50% higher. When medical oncologists and radiation oncologists have greater confidence in the accuracy of these types of results, they can be more aggressive in their clinical decisions and treatments, they can spend less time and money with “second-guessing” procedures, and they can deliver better therapies that have a greater chance of killing the tumor cells and a lesser chance of needless side effects. Thus with the increased confidence of evolving imaging technology, oncologists provide better and safer treatment. Moreover, now that we have the appropriate tools to monitor tumor activity, we are seeing more rapid development of improved therapies, such as highly targeting radiation therapies and novel molecular approaches to cancer therapy, such as gene therapies or immunologic therapies.

As I just mentioned, CMS, as the hallmark of payer reimbursement has, in fact, limited utilization and dramatically limited over-utilization by imposing strict clinical guidelines for when a patient is and is not eligible for a PET study. CMS has recently acknowledged that those guidelines, in fact, are impeding both the appropriate care of many patients and the ability of the PET community, the oncologic community, and CMS to learn more about which patients should and should not undergo PET imaging. CMS has worked with the Academy of Molecular Imaging, the American College of Radiology, and others to address this problem by establishing the National Oncologic PET Registry, which allows for some expansion of the guidelines under which PET studies can be performed for Medicare’s cancer patients, provided that data regarding the impact of PET on patient management are collected. This allows us and CMS to take an organized approach to expanding the use of a new modality into new patient conditions while gathering data to determine whether the new modality actually changes patient management and is, therefore, worthy of continued reimbursement for those conditions. This is a shining example of how the imaging community, the oncology community, and CMS can work together, using what is commonly called “evidence-based medicine” to ensure that a

relatively expensive test is made available to patients who will benefit from it, while still limiting its use to appropriate situations.

In addition, several payers have also established frequency guidelines, based on the concern that repetitive testing is adding more cost than benefit to the patient care equation. Some of those have been reasonable, while some, in my opinion, have not been adequately vetted in the real world of patient management. Recently, I have been involved in a PET stakeholder work group assembled by Dr. Mitchell Burken of Trailblazer, one of CMS's carriers, aimed at establishing appropriate frequency guidelines for various cancer conditions and patient situations, and I believe his approach should be duplicated on a larger scale within CMS. What I need to stress is that such clinical guidelines MUST be developed with input from the folks on the front lines: medical oncologists and radiation oncologists who are treating the patients and imaging physicians experienced in the use of PET in patient management. I would extrapolate those last comments to other imaging modalities.

While thoughtful, collaborative efforts such as those I just described are, in my professional opinion, the appropriate way to balance proper patient care with sound fiduciary responsibility, I don't see how the drastic spending cuts called for in the Deficit Reduction Act of 2005 will stop the inappropriate use of medical imaging. I am concerned that this legislation will deny access to the medical procedures that Medicare patients need. I admit to you today that I am not a businessman. I pursued a career in science and medicine, in part, to AVOID having to deal with business and finance. What I DO know is that the impetus, by both CMS and caregivers, over the past 15 years has been to push cancer care out into the community, while maintaining state-of-the-art quality. This is good for the patients, who no longer have to drive long distances during their very serious illnesses for their diagnostic and therapeutic procedures. This is good for CMS and other payers, because community-based care is typically less expensive than care delivered in large medical centers. We believe that the drastic cuts in imaging reimbursement, particularly for PET and PET/CT, contained in the DRA constitute a serious threat to cancer care in the community. The estimates of the PET community are that the reimbursement cuts contained in the DRA could result in half of the non-hospital-based PET and PET/CT providers closing their doors, because they would be operating at a substantial loss. The net effect will surely be to push cancer care services back into the large hospital setting, translating into greater inconvenience and difficulty for patients and their loved ones and more expense for the healthcare system. Even worse, there are many patients who simply will not undergo advanced imaging tests like PET, because they are unwilling or unable to travel to a distant imaging center or because the lack of proximity means that their community physicians will remain unfamiliar with this life-saving technology.

We believe these cuts in reimbursement are arbitrary, and attempt to balance far too much of the overall healthcare budget on the small percentage that represents imaging. We also believe that there ARE no reliable cost data available by which to justify these cuts. The Academy of Molecular Imaging is currently trying to collate such data for PET and PET/CT and, at the very least, these drastic cuts should be delayed until reasonable

and reliable cost data for both hospital and community outpatient care delivery systems can be gathered and analyzed.

In January 2000, the editorial board of the New England Journal of Medicine listed medical imaging as one of the eleven most significant medical advances of the past 1000 years, ranking on a par with the development of antibiotics and the elucidation of human anatomy and physiology.

The advancement of imaging science, and the ability of cancer patients in all communities across America to access these imaging techniques, must keep pace with the advances in cancer therapy. Optimal cancer care is absolutely dependent on optimal imaging care. To better SEE disease is to better TREAT disease, and the best treatments in the world may be useless if they are not targeted appropriately. To take our American cancer patients, who otherwise have access to the finest cancer care in the world, and restrict their access to high-quality imaging services such as PET, is the medical equivalent of putting them in a very expensive, very fast, sports car – and then bashing the windshield with a ball-peen hammer.

Simply put, Draconian, across-the-board cuts in imaging reimbursement are NOT an effective way to cut overall healthcare costs. CMS should, instead, continue to work with experts in the related imaging and patient-care subspecialties to develop appropriate guidelines for patient management – management that includes, and depends upon, advanced medical imaging.

Mr. Chairman, thank you again for allowing me the opportunity to address you and your distinguished colleagues on this important issue.